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PRE-APPEAL BRIEF REQUEST FOR REVIEW	Docket Number (Optional) 292-PDD-99-20-CON-[70P2]	
	Application Number 10/603,952	Filed June 25, 2003
	First Named Inventor Peter L. Harris et al.	
	Art Unit 3738	Examiner D. H. Willse

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant /inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 45,218
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____

/Todd W. Wight/
Signature

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January 18, 2011
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

- [ ] *Total of 1 forms are submitted.

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: January 18, 2011 Electronic Signature for Kari Lynn Barnes: /Kari Lynn Barnes/

Docket No.: 292-PDD-99-20-CON-[70P2]
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Peter L. Harris et al.

Application No.: 10/603,952 Confirmation No.: 3111

Filed: June 25, 2003 Art Unit: 3738

For: VASCULAR PROSTHESIS Examiner: D. H. Willse

ARGUMENTS IN SUPPORT OF PRE-APPEAL BRIEF PANEL REVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants respectfully submit the following argument in support of the Pre-Appeal Brief Request for Review filed concurrently herewith.

In a Final Office Action, dated September 16, 2010, claims 1-5, 7-11, 14, 16, 18, 19, and 21 were rejected under 35 U.S.C. § 102(b) as anticipated by USPN 5,156,619 to Ehrenfeld ("Ehrenfeld"); claims 6, 15, 17, 20, and 22 were rejected under 35 U.S.C. § 103(a) as unpatentable over Ehrenfeld; claim 27 was rejected under 35 U.S.C. § 103(a) as unpatentable over USPN 4,530,113 to Matterson ("Matterson"); claims 1-5, 7, 14, 16, 18, 19, 21, and 27 were rejected under 35 U.S.C. § 102(e) as anticipated by USPN 5,782,916 to Pintauro et al. ("Pintauro"); claims 6, 15, 17, 20, and 22 were rejected under 35 U.S.C. § 103(a) as unpatentable over Pintauro.

Ehrenfeld shows and describes a flanged end-to-side vascular graft having an integrally formed flange at one end. (Ehrenfeld, Abstract.) "Graft 11 is formed of a polyester fiber, either knit or woven, compacted and given a series of circular crimps 16 about main body 12 and legs 13

and 14." (Ehrenfeld, col. 2:2-5.) "In order to use graft 11 for an end-to-side anastomoses, graft 11 has been cut along a line 18. This provides a flanged graft 21 as shown in FIG. 2 having a straight portion 22 with an integrally formed flange portion 23." (Ehrenfeld, col. 2:6-9.)

Independent claim 1 recites a "tubular portion including a generally uniform surface and a first diameter that tapers to a smaller second diameter." Ehrenfeld fails to show or describe a generally uniform surface, as claimed, since it comprises the crimp along its length. Even assuming *arguendo* that the crimped surface is uniform, Ehrenfeld still fails to identify the taper to a smaller second diameter as claimed. The Office asserts that the crimped surface of Ehrenfeld creates the generally uniform surface with an associated diameter. As claimed, the uniform surface has a first diameter. As such, the minimum, maximum, or some intermediate diameter taken to correspond to the crimped surface of Ehrenfeld is the defined diameter for that section. The entire crimped section is associated with that defined diameter, regardless the location along the crimp, i.e. at the peak or valley. As the entire tube has the same diameter as defined by the "uniform surface," there is no taper. Since the Examiner has taken the crimped surface as the uniform surface, then the taper would have to be of the crimped surface and not caused by the crimp itself. No such feature is shown or suggested by Ehrenfeld. Instead, Ehrenfeld shows the opposite as two separate tubes expand to the space of a single tube. As such, the diameters of the two adjacent tubes would increase to the diameter of the single enlarged tube.

Independent claims 18 and 21 recite "the tube comprising a first diameter portion extending along a majority of the length of the tube." As the crimps of Ehrenfeld create a variable diameter along the entire length of the graft, there is not a section that can be considered a first diameter portion, as claimed. Even assuming *arguendo* that the crimps are defined as a first diameter portion, the tube does not have a second diameter portion less than the first diameter portion. Similar to independent claim 1, the crimped surface would have to be defined as the first diameter portion since it is the crimp that extends along a majority of the length of the tube. Ehrenfeld fails to show or describe a second diameter portion not of the same crimp as the first diameter portion having a smaller diameter.

Matterson shows and describes a graft prostheses woven with cross-weave patterns to prevent unraveling and to increase suture hold strengths. (Matterson, Abstract.) "The graft 10, which is initially woven in a flat tubular configuration as two overlaid, interconnected sheets, is appropriately shaped into its final configuration. The woven tube is placed on a cylindrical mandrel and then crimped." (Matterson, col. 6:46-50.) "To avoid kinking the graft 10 while connecting it to the two openings 42 through the side of a generally straight-line blood vessel, the ends 44 of the graft are cut at an angle oblique to the axis of the graft." (Matterson, col. 7:7-11.)

Claim 27 recites a tube having a first portion with a constant inner dimension and a second portion with a variable inner dimension along a second portion of the central axis. As Matterson is simply a tube with an oblique cut end, the inner dimension along the central axis does not change. The asserted inner arc lengths are not along the central axis, and thus are irrelevant to the claimed variable inner dimension. The diameter of the tube also does not change, as the diameter is measured from a perimeter to perimeter through the center of an object. ("Diameter," The Free Dictionary, http://www.thefreedictionary.com/diameter, "a straight line segment passing through the center of a figure … and terminating at the periphery.") Therefore, the diameter is defined by the tube, from which the end is cut. Similarly, the inner dimension is the size or extent of the inside of the tube. As such, the inner dimension of the tube along the central axis does not change by the oblique cut at the end of the tube, but is instead defined by the tube itself.

Similarly, Matterson fails to show or describe the non-circular opening defining a cross-sectional area that is larger than a cross-sectional area of the first portion of the tube. The cross-sectional area of the Matterson tube is constant, similar to its diameter, and inner dimension. Cross-sectional area is taken at right angles to the axis. ("Cross-section," Merriam Webster, www.Merriam-webster.com/dictionary/cross+section, "a cutting or piece of something cut off at right angles to an axis.") The pertinent axis of Matterson is the longitudinal axis of the tube. Accordingly, any section taken at right angles to the longitudinal axis of the tube would have the same cross sectional area, since the dimensions of the tube are unaltered. Moreover, if the Examiner's position is taken with respect to the definition of the inner dimension (i.e. the dimension is considered to decrease along the oblique end cut), then the cross-sectional area of the end would

similarly decrease such that the cross-sectional area of the end opening is actually less than the enclosed tube portion.

Pintauro shows and describes a prosthetic device for controlling urinary continence. (Pintauro, Abstract.) The valve assembly includes a tubular body 12 and "a first anchor 14. The first anchor preferably conforms to a portion of a base 32 of a bladder 30 as illustrated in FIGS. 4 and 5. The first anchor 14 functions to releasably secure the valve assembly 10 relative to the bladder 30 and the urethra 40." (Pintauro, col. 3:44-48.) The anchor is mechanically biased in the direction of an enlarged configuration to help prevent the valve assembly from being expelled distally from the urethra. (Pintauro, col. 3:60-4:3.) Reinforcing rings 15 and/or 17, fine gauge spring wire, spring bias, or flexible struts may be used to provide adequate anchoring while minimizing the total contact area of the anchor. (Pintauro, col. 4:21-44.) "The valve assembly 10 also includes a valve 24, such as a duckbill valve, which is preferably located within the fluid flow path through tubular body 12 between the proximal end 18 and the distal end 20." (Pintauro, col. 5:7-10.) "FIGS. 12 and 13 illustrate the kinking feature of the tubular body 112 .... As can be seen, during the hypermobility event, the proximal portion of the tubular body 112 kinks or collapses, which helps to maintain continence without having to unduly increase the opening pressure of the valve 124." (Pintauro, col. 7:60-8:2.)

Independent claims 1, 18, 21, and 27 recite a vascular prosthesis. In contradistinction to the assertions made in the Office Action, the Pintauro device is not capable of connection to a blood vessel opening. Instead, the Pintauro device is designed and configured for implantation into the bladder and urethra without direct attachment to tissue. The Pintauro attachment is achieved by the expansion of the anchor 14 through reinforcing rings, spring wires, flexible struts, etc. The Pintauro expansion structures prevents the Pintauro anchor from conforming to a blood vessel and permitting attachment therebetween. Instead, these structures would distort and traumatize a blood vessel if the Pintauro prosthesis were used as a vascular prosthesis as proposed by the Office. Moreover, the addition of the valve within the fluid flow path to close the fluid flow for low pressure differentials would stop the flow of blood if used as a vascular prosthesis as proposed. Accordingly, Pintauro does not show or describe a prosthesis properly capable of connection to a blood vessel opening, as

asserted by the Office. Moreover, the asserted reduced diameter section of Pintauro is provided by a "kinking feature" of the prosthesis. As is known in the art, kinking and collapse of a vascular prosthesis is not desirable as it obstructs blood flow in the patient, leading to potentially undesirable outcomes. Therefore, even assuming *arguendo* that the valve would be a desirable feature to regulate fluid for a given pressure, the uncontrolled kinking of the prosthesis results in a device unsuitable for vascular applications.

Dependent claims 2, 4, and 8-9 stand rejected over Ehrenfeld and/or Pintauro. However, these references fail to show or describe a first diameter parallel to an axis of the tubular portion corresponding to a heel and a toe of the end formation, since a perimeter of the asserted enlarged chamber does not enclose any line at both ends along the claimed axis. Moreover, since a surface does not enclose the first diameter, there is no transition from the tubular portion to either a heel or toe to define as concave or convex, as claimed. As such, Ehrenfeld and/or Pintauro fails to show or describe these features.

In conclusion, Applicants respectfully request review of the rejections under 35 U.S.C. § 102 and § 103 over Ehrenfeld, Matterson, and Pintauro. Due to space restrictions, Applicants do not address with specificity the rejection of all of the contentions of the Office, but expressly reserve the right to argue these positions during appeal. Applicants' positions are presented here in summary form, a more developed discussion is a matter of record in the prosecution history and can be found, for example, in the Responses filed November 15, 2010 and July 6, 2010.

Dated: January 18, 2011

Respectfully submitted,

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